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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,143	JACKSON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,14-37 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 14-37 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendments

1) Acknowledgment is made of Applicants' amendment filed 07/11/07, 05/16/07 and 01/12/07 in response to the non-final Office Action mailed 10/12/06. The former is compliant with 37 CFR 1.121. Applicants have amended the specification and the claims.

Status of Claims

2) Claims 8-13 and 38-51 have been canceled via the amendment filed 07/11/07.

Claims 1-7, 14, 19, 21, 22, 27, 29, 30, 35 and 37 have been amended via the amendment filed 07/11/07.

New claim 52 has been added via the amendment filed 07/11/07.

Claims 1-7, 14-37 and 52 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to the specification made in paragraph 7(a) of the Office Action mailed 10/12/06 is withdrawn in light of Applicants' amendment to the specification.

6) The objection to the specification made in paragraph 7(b) of the Office Action mailed 10/12/06 is withdrawn in light of Applicants' amendment to the specification.

7) The objection to the specification made in paragraph 7(c) of the Office Action mailed 10/12/06 is withdrawn in light of Applicants' amendment to the specification.

Objection(s) Maintained

8) The objection to claim 2 made in paragraph 7(c) of the Office Action mailed 10/12/06 is

maintained for reasons set forth therein and herein below. Although Applicants have amended a part of the specification to address the issue, several other trademark recitations continue to appear in the instant specification. For example, see 'Marcol 52' at line 28 of page 24. It is suggested that Applicants examine the whole specification and capitalize all trademark recitations, wherever such recitations appear.

Rejection(s) Moot

9) The rejection of claims 8 and 9 made in paragraph 9 of the Office Action mailed 10/12/06 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claims 8 and 9 made in paragraph 11 of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

11) The rejection of claims 8 and 9 made in paragraph 14 of the Office Action mailed 10/12/06 under 35 U.S.C § 102(b) as being anticipated by Quaissi *et al.* (*Science* 234: 603-606, 1986) as evidenced by Qin *et al.* (*J. Immunol.* 150: 2072-2080, 1993) and Haites *et al.* (*J. Biol. Chem.* 280: 10981-10987, 2005), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

12) The rejection of claim 7 and those dependent therefrom made in paragraph 9 of the Office Action mailed 10/12/06 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claim 1 made in paragraph 11(a) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 1 made in paragraph 11(b) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claim 2 made in paragraph 11(c) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants'

amendment to the claim.

16) The rejection of claim 3 made in paragraph 11(d) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 4 made in paragraph 11(e) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 5 made in paragraphs 11(f) and 11(g) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 6 made in paragraph 11(h) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claim 4 made in paragraph 11(j) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

21) The rejection of claim 19 made in paragraph 11(l) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

22) The rejection of claim 21 made in paragraph 11(m) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

23) The rejection of claim 27 made in paragraph 11(n) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

24) The rejection of claim 29 made in paragraph 11(o) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

25) The rejection of claim 35 made in paragraph 11(p) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

26) The rejection of claim 37 made in paragraph 11(q) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

27) The rejection of claims 2-7 and 14-37 made in paragraph 11(r) of the Office Action mailed 10/12/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

28) The rejection of claims 1-4, 14, 16, 18, 19, 22, 24, 26, 27, 30, 32, 34 and 35 made in paragraph 13 of the Office Action mailed 10/12/06 under 35 U.S.C. § 102(b) as being anticipated by Brodeur *et al.* (*Infect. Immun.* 50: 510-516, 1985) as evidenced by Rodriquez *et al.* (US 5,286,484), is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

29) The rejection of claims 5-7 and 14-37 made in paragraph 14 of the Office Action mailed 10/12/06 under 35 U.S.C § 102(b) as being anticipated by Quaissi *et al.* (*Science* 234: 603-606, 1986) as evidenced by Qin *et al.* (*J. Immunol.* 150: 2072-2080, 1993) and Haites *et al.* (*J. Biol. Chem.* 280: 10981-10987, 2005), is withdrawn in light of Applicants' amendment to the claims.

New Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

30) Claims 1 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended, includes the new limitation: 'or a polypeptide at least 90% identical thereto and having a molecular weight of 44 kD to 55 kD as determined in SDS-PAGE, wherein the polypeptide is a polypeptide of *Neisseria meningitidis*'. The amendment to claim 1 deletes the previous limitation 'NMASP', and thereby broadens the scope of the claim. A generic polypeptide at least 90% identical to any isolated *N. meningitidis* polypeptide having a molecular weight of 44

kD to 55 kD as determined by SDS-PAGE, including a non-NMASP polypeptide, encompasses a truncated *N. meningitidis* polypeptide that has 10% of the amino acids deleted, i.e., a polypeptide that lacks 10% of the amino acids, and that still has a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE. However, there is no descriptive support in the instant specification for a *Neisseria meningitidis* polypeptide that is at least 90% identical to an isolated polypeptide having a molecular weight of 44 kD to 55 kD as determined in SDS-PAGE and having a molecular weight of 44 kD to 55 kD as determined in SDS-PAGE. Applicants state that the amendment is supported at least in paragraph 0046. However, there is no paragraph that is identified as paragraph 0046 in the instant specification, as originally filed. The original claim 1 and the first and second paragraphs under the 'Detailed Description of the Invention' are supportive of an isolated meningococcal NMASP having a molecular weight of about 40 kD to about 55 kD, preferably about 44 kD to about 53 kD as determined by SDS-PAGE. The currently claimed polypeptide however encompasses a non-NMASP polypeptide of *Neisseria meningitidis* having the recited molecular weight, for which there is no support. Furthermore, an isolated truncated polypeptide with 10% of the amino acids deleted would not be expected to have the same molecular weight as the non-truncated polypeptide from which it is derived. Therefore, the above-identified limitation in the instant claim(s) is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

31) Claim 7 and dependent claims 15, 17, 20, 21, 23, 25, 28, 29, 31, 33, 36 and 37 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 7, as amended, is drawn to an isolated peptide 'consisting of an immunogenic fragment of 7 or more amino acids of a polypeptide of *Neisseria meningitidis* having a molecular weight of '44 kD to 55 kD' as determined by .... SDS-PAGE'. The amendment to claim 7 deletes the previous limitation 'NMASP', and thereby broadens the scope of the claim. As currently claimed, the peptide encompasses a peptide consisting of an immunogenic fragment of 7 or more amino acids of a non-NMASP polypeptide of *N. meningitidis* having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE. Applicants state that support for the limitation '7 or more' can be found in the first paragraph under Section 5.2 on page 13. However, this part of the disclosure is limited to a fragment of the 'NMASP' polypeptide of *N. meningitidis* having a molecular weight of 44 kD to 55 kD or 44 to 53 kD as determined by SDS-PAGE wherein the fragment has 7 or more amino acids of said NMASP. This part of the specification does not identify the peptide 'consisting' of seven amino acids of the NMASP polypeptide, let alone any other polypeptide of a molecular weight of 44 kD to 55 kD, to be 'immunogenic'. Therefore, the above-identified limitation in the instant claim(s) is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

32) Claim 1 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure which is not enabling. Claim 1 is not enabled because the sequence identifying (SEQ ID) number for the isolated *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE, critical or essential to the practice of the invention, is not included in the claim(s). *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The feature of being 'at least 90% identical' to an isolated *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE is essential for the

claimed polypeptide. However, the SEQ ID number of the isolated *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE is not recited in claim 1. As illustrated under art rejections(s) previously and herein below, *N. meningitidis* produces several polypeptides having a molecular weight in the range of 44 kD to 55 kD as determined by SDS-PAGE, the precise structure of all of which is not known. The claim lacks the critical limitation with regard to the amino acid sequence of *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE, without which one of ordinary skill in the art cannot perform the structural comparison, and practice the invention as currently claimed. The instant claim does not structurally identify the recited *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE by a sequence ID number. A polypeptide having at least 90% identity can be obtained only when the sequence(s) to be compared is identified in the claim(s) by a specific structure or SEQ ID number. Without such a disclosure, undue experimentation would have been required by one of ordinary skill in the art to practice the invention as claimed.

33) Claim 7 and dependent claims 15, 17, 20, 21, 23, 25, 28, 29, 31, 33, 36 and 37 are rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure which is not enabling. Claim 7 is not enabled because the sequence identifying number for the recited *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE, critical or essential to the practice of the invention, is not included in the claim(s). *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The feature of 'consisting' of an immunogenic fragment of '7 or more amino acids' of a *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE is essential for the claimed peptide product. However, the SEQ ID number of the recited *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE is not recited in the claim. *N. meningitidis* produces several polypeptides having a molecular weight in the range of 44 kD to 55 kD as determined by SDS-PAGE, the precise structure of all of which is not known. The claim lacks the critical limitation with regard to the amino acid sequence of *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE, without which one of ordinary skill in the art cannot identify and obtain a 7 or more amino

acid-long peptide as currently claimed. The instant claim does not structurally identify the recited *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE by a specific sequence ID number. A peptide consisting of an immunogenic fragment of 7 or more amino acids as recited can be obtained only when the sequence(s) from which it is obtained is recited by identifying the polypeptide with a SEQ ID number. Without such a disclosure, undue experimentation would have been required by one of ordinary skill in the art to practice the invention as claimed.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

34) Claims 1-7, 14-37 and 52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1, as amended, is indefinite and confusing in the limitation: 'a polypeptide at least 90% identical thereto and having a molecular weight of 44 kD to 55 kD as determined in SDS-PAGE'. It is unclear how a polypeptide having at least 10% non-identity to a 44 kD to 55 kD polypeptide can have a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE. Does it mean that a polypeptide having at least 10% of the amino acid residues deleted from a 44 kD to 55 kD polypeptide would also have a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE?

(b) Claim 1, as amended, is indefinite in the limitation: 'a polypeptide at least 90% identical thereto', because it is unclear what is encompassed in this limitation. Since there is no SEQ ID number recited in the claim, it is unclear whether 90% identity represents 90% functional identity.

(c) Claim 1 is vague and indefinite in the limitation 'a polypeptide at least 90% identical thereto'. The claim neither identifies the amino acid sequence of the isolated *N. meningitidis* polypeptide having a molecular weight of 44 kD to 55 kD as determined by SDS-PAGE, nor the amino acid sequence of a polypeptide at least 90% identical thereto for one of skill in the art to perform the comparison, or to envisage the metes and bounds of the claim. It is unclear how the percent identity of at least 90% is determined, i.e., in comparison to what other SEQ ID number. The only comparable structural limitation of the polypeptide recited in the instant claim is the

molecular weight of the polypeptide. However, one cannot use molecular weight to obtain a certain percent identity.

(d) Claim 3, as amended, is vague, indefinite and/or confusing in the limitation: 'serogroup Types A-L and W', because it is unclear what is encompassed in the limitation 'serogroup Types A-L and W'. Do the 'serogroup Types' represent *Neisseria meningitidis* serotypes, immunotypes, subtypes, or serogroups?

(e) Analogous rejection and criticism apply to claim 4, as amended, with regard to the limitation: 'serogroup Type A, Type B, Type C or Type W'.

(f) Claim 6 is indefinite and confusing in the Markush language: 'selected from the group consisting of SEQ ID NO: 11'. Since there is only one Markush species, it is suggested that Applicants replace the above-identified limitation with the limitation --of SEQ ID NO: 11--.

(g) Claims 2-6, 14-37 and 52, which depend directly or indirectly from claim 1 or claim 7, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

35) Claims 1-4, 14, 16, 18, 19, 22, 24, 26-30, 32 and 34-37 are rejected under 35 U.S.C § 102(b) as being anticipated by Allunans *et al.* (*APMIS* 106: 1181-1187, December 1998) as evidenced by Schlecht *et al.* (*Naturwissenschaften* 80: 9-17, 1993, abstract).

Instant claims are granted the effective filing date of the instant application due to the new matter identified above, and therefore Allunans *et al.* qualifies as prior art under 35 U.S.C § 102(b).

The limitation 'vaccine' in claims 22, 24 and 26-29 represents the intended use of the claimed polypeptide composition and therefore is not given any patentable weight in this rejection.

Allunans *et al.* taught an isolated or purified polypeptide of a serogroup (i.e., serogroup Type) A *Neisseria meningitidis* having a molecular weight of 47-48 kDa as determined in SDS polyacrylamide gel electrophoresis and contained in a phosphate buffer. See abstract; Figure 3; paragraph bridging pages 1185 and 1186; paragraph bridging two columns on page 1183; Materials and Methods; and section 'SDS-polyacrylamide electrophoresis on page 1183. The molecular weight of the prior art polypeptide falls well within the recited range of '44 kD to 55 kD' and '44 to 53 kD' and therefore, the prior art isolated or purified polypeptide anticipates the instantly claimed

polypeptide. Since the prior art polypeptide is not fully purified, it is expected to contain at least residual or contaminant phospholipids, or cell wall components such as OMP, lipoprotein, and the meningococcal lipopolysaccharide immunogen. Because of the overlapping molecular weight and the bacterial origin of the prior art polypeptide, the prior art polypeptide is viewed as the same as the polypeptide claimed in the instant claims, and therefore it is expected to have the same intrinsic structure and properties as that of the Applicants' polypeptide. That one or more of the residual cell wall components such as OMP, lipoprotein, and the meningococcal lipopolysaccharide in the prior art polypeptide serve as intrinsic immunoadjuvants is inherent from the teachings of Allunans *et al.* in light of what is well known in the art. For example, Schlecht *et al.* taught that bacterial cell wall components such as lipopolysaccharides, a variety of membrane proteins, murein, and lipoprotein act as immunoadjuvants. See abstract of Schlecht *et al.*

Claims 1-4, 14, 16, 18, 19, 22, 24, 26-30, 32 and 34-37 are anticipated by Allunans *et al.* The reference of Schlecht *et al.* is not used as a secondary reference in combination with the reference of Allunans *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Allunans *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

36) Claims 1-7, 14-37 and 52 are rejected under 35 U.S.C § 102(b) as being anticipated by Jackson *et al.* (WO 00/12535, published 03/09/2000) ('535).

Instant claims are granted the effective filing date of the instant application due to the new matter identified above, and therefore Jackson *et al.* qualifies as prior art under 35 U.S.C § 102(b).

Jackson *et al.* ('535) disclosed an isolated NMASP polypeptide of *Neisseria meningitidis* having a molecular weight of 44 kD to 55 kD, or 44 kD to 53 kD as determined by SDS-PAGE wherein the polypeptide comprises an amino acid sequence that is 100% identical to SEQ ID NO: 11 that is recited in the instant claim 52. Jackson *et al.* ('535) also disclosed the seven amino acid-long peptide, GNSGGPL, of said NMASP polypeptide of *Neisseria meningitidis.* See page 20; and claims 7-9. A vaccine or an antigenic composition comprising the polypeptide or the peptide, with or without a pharmaceutically acceptable carrier, one or more adjuvants, lipids, lipopolysaccharides, proteins, phospholipids, attenuated organisms, and/or inactivated whole cells is taught. The polypeptide is from *Neisseria meningitidis* Types A, B, C, or W, and binds to an antibody that

specifically binds to a protein having the amino acid sequence of SEQ ID NO: 11. See abstract; pages 70 and 71; and claims 5, 6, 1-4, and 14-38.

Claims 1-7, 14-37 and 52 are anticipated by Jackson *et al.* ('535).

Remarks

37) Claims 1-7, 14-37 and 52 stand rejected.

To be consistent with the claim language used in claim 7, it is suggested that Applicants replace the limitation 'as determined in ...SDS-PAGE' in claim 1 with the limitation --as determined by .... SDS-PAGE--.

38) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

39) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

40) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-

9199 (in USA or CANADA) or 571-272-1000.

41) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September 2007

S. DEVI, PH.D.
PRIMARY EXAMINER